

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GILEAD SCIENCES, INC., GILEAD
PHARMASSET LLC, and GILEAD
SCIENCES LIMITED,

Plaintiffs,

v.

ABBOTT LABORATORIES, INC.,
and ABBVIE, INC.,

Defendants.

Civil Action No. 13-2034 (GMS)

ORDER CONSTRUING THE TERMS OF U.S. PATENT NOS. 8,466,159 & 8,492,386

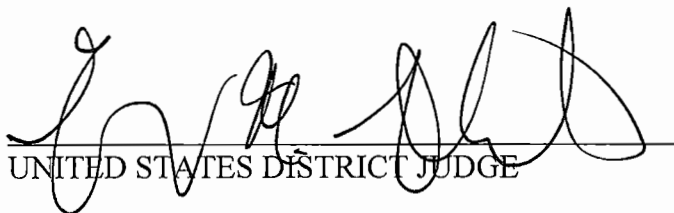
After having considered the submissions of the parties and hearing oral argument on the matter, IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of U.S. Patent Nos. 8,466,159 (the “159 Patent”) and 8,492,386 (the “386 Patent”):

The term **“treatment for HCV”** is construed to have its plain and ordinary meaning.¹

¹ A court should first look to the language of the claim in construing the terms of a patent. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The Court should generally give claim terms their “ordinary and customary meaning” which is “the meaning that the term[s] would have to a person of ordinary skill in the art in question at the time of the invention.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (citations omitted). The plaintiffs Gilead Sciences, Inc., Gilead Pharmasset LLC, and Gilead Sciences Limited (“Gilead”), propose the construction: “give for the purpose of stopping or slowing the progression of HCV,” which the court agrees represents the plain and ordinary meaning of “treatment for HCV.” (D.I. 155 at 11). The court rejects the proposed construction of “medical care to achieve significant efficacy against HCV, as may be measured by sustained virological response (SVR)” submitted by Abbott Laboratories, Inc. and Abbvie, Inc. (“Abbvie”).

Abbvie proposes that the court construe “treatment” to include the metric discussed in the summary of the invention: “administered in amounts effective to provide a sustained virological response (SVR).” (D.I. 158 at 7, 10). However, AbbVie’s construction conflates treatment with efficacy. SVR measures the patient’s response to the treatment. (D.I. 155 at 2); (D.I. 177 at 6-7). The plain meaning does not support a construction in which the method for measuring effectiveness defines the term treatment itself. Moreover, AbbVie’s construction selects just one of the measures of efficacy discussed in the specification. (D.I. 155 at 15); (D.I. 177 at 6). While the court agrees that the goal of a treatment is to be effective, the court does not agree that treatment should be construed in a way that requires

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effectiveness as measured by SVR.

Other courts have reached similar conclusions. In *Schering Corp. v. Mylan Pharm., Inc.*, No. CIV.A. 09-6383 JLL, 2011 WL 2446563 (D.N.J. June 15, 2011), a New Jersey district court held that “to treat a disease does not imply that the progression of the disease will actually be slowed, arrested, or reversed, but the plain meaning of ‘treatment’ does imply a goal of achieving those results.” *Id.* at *5. In *Novartis Pharm. Corp. v. Actavis, Inc.*, No. CV 12-366-RGA-CJB, 2013 WL 6142747 (D. Del. Nov. 21, 2013), a Delaware district court opined that the term treatment should not be constructed to mean effective treatment. The court agreed that ultimately, the plain and ordinary meaning of treating “is to attempt to cause a therapeutic improvement, without necessarily having assurance of what the outcome will be.” *Id.* at *11.

Gilead Sciences, Inc. v. Mylan Inc., No. 1:14CV99, 2015 WL 2238060, (N.D.W. Va. May 12, 2015), does not require us to reach a different result. That case, decided in the Northern District of West Virginia, is not binding on this court and addressed “different patents involving a different disease, different specifications, and different prosecution histories, to support its construction.” (D.I. 177 at 15). In *Gilead Sciences, Inc.*, Gilead argued that treatment means “therapeutically effective treatment.” No. 1:14CV99, 2015 WL 2238060 at *11. The court agreed that “therapeutically effective” did not refer to “treatment” per se, but observed that it was unclear whether the inventors meant to define treatment as any treatment, rather than as a therapeutically effective treatment. *Id.* at *13-14. Relying on extrinsic evidence, Judge Keeley concluded that “doctors would only consider a drug to ‘treat’ an HIV-infected patient if it effectively produced a drop in HIV viral load.” *Id.* at *15. In contrast, in the instant case, this court is persuaded by Gilead’s argument and the evidence presented in the declaration of expert Dr. Afdhal that there were many treatments for HCV that did not seek to attack the virus but still would have been considered treatments for HCV to those of skill in the art. (D.I. 157 at ¶¶ 30-31.) Therefore, the court will adopt the plain and ordinary meaning of “treatment” proposed by Gilead.